CLINICAL UPDATE

Current status of carotid artery stenting

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This Clinical Update summarizes the results of larger case series, industry-sponsored registries, and randomized trials of carotid artery stenting (CAS). In >20 case series that studied >24,000 patients undergoing CAS, 51% of patients were symptomatic, most procedures (97%) resulted in successful stent deployment, and 30-day stroke rates varied from 1% to 8%, with a trend toward lower rates as experience and embolic protection device (EPD) use increased. In 12 industry-sponsored registries (none were published in peer-reviewed journals), 30-day stroke rates varied from 2% to 7%, and 30-day combined adverse events, including stroke, death, and myocardial infarction, were 3% to 9%. More than 12 randomized trials comparing CAS and carotid endarterectomy (CEA) have been initiated since 1998. Results have varied over time, depending on the population studied and the technology used. However, the largest and most recent results of the completed SAPPHIRE trial in high-risk patients undergoing CAS with the use of EPDs demonstrated that CAS is at least not inferior to CEA, with a 1-year combined adverse event rate of 12% for CAS and 20% for CEA ($P = .05$). Other ongoing trials will address not only whether CAS could be superior to CEA in high-risk patients but also, more importantly, whether CAS is beneficial in other subgroups, such as low-risk and asymptomatic patients. (J Vasc Surg 2006;43:406-11.)

Carotid artery stenting (CAS) is increasingly used in place of carotid endarterectomy (CEA) even though few randomized trials have directly compared these alternatives. This is based in part on case series and industry-sponsored registries, many of which have not yet been published in peer-reviewed journals. This Clinical Update reviews the status of CAS based on currently available data.

Case series. Since the advent of CAS in the mid 1990s, >20 case series of at least 99 patients have been published, reporting >24,000 patients (Table I). A weighted average of these studies indicates that 51% of patients treated were symptomatic and >97% received the planned stent. Independent outcome evaluation by a neurologist was performed in 64% of series.

After 2002, embolic protection devices (EPDs) were widely used. In terms of outcomes, 30-day stroke rates varied from 1% to 8%, but there was a trend toward lower rates as experience increased with time and EPD use became more widespread. Overall, the average 30-day stroke rate was 3% across all studies, and the average combined 30-day rate of stroke, myocardial infarction, or death was 4%. These outcomes should be interpreted with caution, however, because rates varied with year of procedure, EPD use, neurologist examination, and patient characteristics. Lastly, early restenosis rates appeared low (1% to 8%), albeit only reported in half the studies.

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Industry-sponsored registries. Results from >10 industry-sponsored trials of specific CAS systems have been presented at national meetings, but none have yet been published in a peer-reviewed journal. All of these registries, except for the Acculink for Revascularization of Carotids in High Risk Patients 1 (ARCHeR 1), routinely used EPDs. (Table II). Stroke rates varied from 2% to 7% at 30 days, and combined adverse outcome measures (stroke, death or myocardial infarction) varied from 3% to 8% at 30 days. A weighted average across these registries showed that 27% of patients were symptomatic, 4% of patients experienced periprocedural strokes, and combined adverse outcome measures were 6% at 30 days.

Two registries have led to device approval by the US Food and Drug Administration (FDA). The ARCHeR registry was utilized by Guidant (Indianapolis, Ind) to obtain United States Food and Drug Administration (FDA) approval for the Accunet/Acculink system, and the SECuRITY registry allowed Abbott (Abbott Park, Ill) to obtain FDA approval for the Xact/Emboshield system. These registries achieved low stroke rates for CAS. It is important to note, however, that in the process of achieving FDA approval, these results were compared with historical controls of CEA in high-risk patients. For example, in ARCHeR, the estimated stroke rate for high-risk patients undergoing CEA was 14.5%. In many centers of excellence, combined adverse event rates after CEA in high-risk patients were much lower than that assumed by these registries, between 5% and 7%[1,2] at 1 year.

Randomized trials. At least 12 trials directly comparing CAS and CEA have been initiated (Table III). All except Clopidogrel and Aspirin for Reduction of Emboli in Symptomatic Carotid Stenosis (CARESS)[3] were randomized controlled trials. All used independent neurologist examinations to determine outcomes. Nearly all trials initi-

Table I. Case series of carotid artery stenting

Study author	*Year*	*Patients/arteries (N)*	*% symptomatic*	*% with stent*	*Dominant stent*	*% with EPD*
Dietrich[22]	1996	110/117	28	99	Palmaz	0
Yadav[23]	1997	107/126	59	100	Variable	0
Bergeron[24]	1999	97/99	44	97	Palmaz	0
Henry[25]	2000	290/315	42	99	Palmaz	52
Shawl[26]	2000	170/192	61	99	Palmaz	0
Roubin[27]	2001	528/604	48	98	Variable	0
Ahmadi[28]	2001	303/320	38	93	Wallstent	0
Criado[29]	2002	132/135	40	98	SMART	0
Guimaraens[30]	2002	164/192	92	99	Wallstent	90
Al-Mubarek[31]	2002	162/164	48	99	Variable	95
Kao[32]	2002	118/129	75	100	Easy Wall	0
Stankovic[33]	2002	100/102	37	97	Variable	67
Kastrup[34]	2003	100/100	63	100	SMART	0
Cremonesi[35]	2003	442/442	57	99	Wallstent	100
Wholey[36†]	2003	11234/12392	53	98	Variable	38
Cernetti[37]	2003	100/104	23	99	Variable	98
Hobson[38]	2003	105/114	39	100	Wallstent	25
Hobson[5]	2004	749/749	31	99	Acculink	88
Sztriha[39]	2004	245/260	53	99	Wallstent	0
Henry[40]	2004	246/272	64	100	Palmaz	99
Riemers[41]	2004	753/808	26	100	Multiple	100
Theiss[21]	2004	3270/3853	56	93	Multiple	64
Sganzerla[42]	2004	94/100	34	100	Variable	100
Vos[43]	2005	509/509	33	98	Wallstent	30
Yen[44]	2005	174/174	36	100	Acculink	100
Boseirs[45†]	2005	2712/2172	41	99	Multiple	85
Zahn[46]	2005	1734/1841	55	100	Multiple	42

Neuro MD, Independent neurologic evaluation by a neurologist; *MI,* myocardial infarction; *EPD,* embolic protection device.
This list represents all case series reported in peer-reviewed journals with greater than or equal to 99 patients or arteries.
Stent type or EPD type reported as "multiple" if there was not a dominant type used.
Stent type or EPD type reported as "variable" if stents or EPDs were not used on each patient in the series.
In some registries, individual patients experienced multiple adverse events. Therefore combined rate is not always additive.
*Combined complications included carotid dissection and intracranial hemorrhage.
†Self reported multi-practitioner registry, not a case series.
‡Some results in this series represent 69 day results, not 30-day results.

Table II. Trials of carotid artery stenting

Name	*Patients (N)*	*Year results presented*	*Published in peer-reviewed journal*	*% symptomatic*	*Stent*	*Embolic protection device*	*30-day stroke %*	*30-day death %*	*30-day MI %*	*30-day combined %*
SECuRITY[47]	305	2003	No	Not reported	Xact	Emboshield	6.9	0.3	0	7.2
ARCHER1[48]	158	2004	No	25	Acculink	None	4.4	2.5	2.5	7.6
ARCHeR2[48]	278	2004	No	24	Acculink	Accunet	2.2	5.8	2.9	8.6
ARCHeR3[48]	145	2004	No	21	Acculink	Accunet	1.4	6.2	0.7	8.3
MOMA[49]	157	2005	No	Not reported	Variable	MOMA	5.7	—	0	5.7
PRIAMUS[49]	416	2005	No	63	Variable	MOMA	4.2	0.4	—	4.6
PASCAL[49]	113	2005	No	Not reported	Exponent	Variable	—	—	—	8.0
MAVERiC[50]	498	2004	No	24	Exponent	Guardwire	2.0	2.0	1.2	5.1
CREATE[51]	419	2004	No	17	Protégé	Spider	3.3	1.0	0.5	4.8
BEACH[52]	480	2005	No	25	Wallstent	Filterwire	4.2	1.5	0.8	5.8
CABERNET[53]	433	2005	No	24	NexStent	Filterwire	3.4	0.5	0.2	3.8
SHELTER[54]	—	—	No	—	Wallstent	Guardwire Plus	—	—	—	—

Neuro MD, Independent neurologic evaluation by a neurologist; *MI,* myocardial infarction.
Trials reported in chronological order of when results were presented. In some registries, individual patients experienced multiple adverse events; therefore combined rate is not always additive.

ated after 2001 utilized EPDs. Unlike the other trials, CARESS assigned patients to CAS or CEA via "selection criteria reflective of broad clinical practice."[3] CARESS achieved some of the lowest stroke and overall complication rates reported across all trials for both CAS and CEA, indicating the possibility that careful patient selection may be one of the most important determinants of outcome for both CAS and CEA.

Table I. Continued.

Dominant EPD	*Neuro MD*	*30-day stroke %*	*30-day death %*	*30-day MI %*	*30-day combined %*	*Restenosis %*	*Follow-up (months)*
None	No	6.4	0.9	—	10.9	3.4	3
None	Yes	7.0	0.9	—	7.9	4.9	6
None	Yes	5.0	0.0	0.0	5.0	3.0	13
Percusurge	Yes	4.2	0.3	—	—	4.7	13
None	Yes	2.9	0.0	0.0	0.0	2.0	19
None	No	5.8	0.0	0.0	7.4	3.1	36
None	Yes	7.8	0.6	0.0	8.4	8.0	12
None	No	3.0	0	0.0	3.0	3.0	16
Variable	No	1.0	1.9	—	3.0	4.1	12
Neuroshield	Yes	1.0	1.0	0.0	2%	—	—
None	No	2.4	2	—	2.4	3.1	16
Neuroshield	Yes	7.0	0.0	0.0	7.0	3.4	12
None	No	7.0	1.0	0.0	8.0	—	—
Angioguard	Yes	1.1	0.0	0.0	3.4*		30 days
Variable	No	4.0	0.8	—	4.8	2.4	36
Percusurge	Yes	3.0	1.0	1.0	5%	1.8	24
Accunet	Yes	1.0	2.0	1.0	3.0	3.8	26
Accunet	Yes	4.0	0.8	—	4.4.	—	—
None	Yes	3.1	0.4	0.0	3.5	—	—
Percusurge	No	1.9	0.4	0.0	2.3	0.5	23
Multiple	Yes	5.6	0.1	0.0	5.7	—	—
Multiple	Yes	2.5‡	0.6‡	—	2.8^		
Variable	Yes	5.0	0.0	0.0	5.0	—	—
Filterwire	Yes	3.7	1.0	0	4.7	—	—
Angioguard	Yes	1.7	1.7	—	3.4	—	—
Multiple	No				1.2	3.4	72
Emboshield	No	3.0	0.8	—	3.8	—	—

Although 7 of the 12 trials have publicly reported outcomes, the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial is most widely cited because it reported 2-year results with uniform usage of EPDs. In this trial, 334 patients who were considered high risk for CEA were randomized to CEA or CAS.[4] High-risk was defined as having at least one of the following risk factors: clinically significant heart disease, severe pulmonary disease, contralateral carotid occlusion, contralateral laryngeal nerve palsy, previous radical neck surgery or radiation therapy to the neck, recurrent stenosis after endarterectomy, or age >80 years. The combined 30-day end point of stroke, death, or myocardial infarction was 4.4% for CAS vs 9.8% for CEA ($P = .06$). At 1 year, this combined end point was 12% for CAS vs 20% for CEA ($P = .05$). The authors concluded that carotid stenting with embolic protection is not inferior to CEA in high-risk patients. This trial was terminated early when recruitment slowed; it is likely that a larger trial would have shown CAS to be superior to CEA in high-risk patients as defined in this study.

Multiple ongoing randomized controlled trials are focused on both high- and lower-risk patients, including Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST),[5] International Carotid Stenting Study (ICSS),[6] Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE)[7], Endarterectomy Versus Angioplasty in Patients with Severe Symptomatic Carotid Stenosis (EVA-3S),[8] and Asymptomatic Subjects with Significant Extracranial Carotid Occlusive Disease Trial" (ACT I).[9] CREST is a randomized trial comparing CEA and CAS in low-risk patients with both symptomatic stenoses ≥50% and asymptomatic stenoses ≥80%. As part of the lead-in phase to this study, 749 patients (31% symptomatic) underwent CAS. Thirty-day stroke-death rates increased with age such that there was a 12.1% 30-day stroke-death rate for patients ≥80 years old compared with 3.2% for patients <80 years of age. ICSS, SPACE, and EVA-3S are randomizing symptomatic patients, while ACT I is randomizing asymptomatic patients.

Embolic protection devices. Most current data suggest that CAS can be performed with acceptable stroke rates only with the use of EPDs.[10] The first use of an EPD in CAS was described in France in the 1990s.[11] Since then, many different devices have been developed (Table IV). Most of these are wire-based filters that trap embolic debris. Currently, the Guidant ACCUNET Filterwire[12] and the Abbott Emboshield[13] are the only FDA-approved EPDs for use with CAS in the United States.[14] In addition to filters, distal internal carotid artery balloon occlusion with subsequent aspiration can be used for embolic protection (GuardWire, Medtronic, Minneapolis, Minn[15]) as well as flow blockage in the internal carotid artery with common and external carotid balloon occlusion (MOMA, Invatec, Roncadelle, Italy[16]), or flow reversal in the internal carotid artery with the Parodi Anti-Emboli System (W. L. Gore & Associates, Flagstaff, Ariz[17]). Different devices may have advantages in selected patients based on device size, lesion characteristics, internal carotid artery tortuosity, and other

Table III. Randomized trials of carotid artery stenting

Name	*CAS patients*	*CEA patients*	*Year results presented*	*Published in a peer-reviewed journal?*	*Dominant stent*	*Dominant EPD*	*Neuro MD*
Naylor et al [55]	7	10	1998	Yes	None	None	Yes
Alberts et al[56]	107	112	2001	Yes	Wallstent	None	Yes
Brooks et al[57]	52	52	2001	Yes	Variable	Variable	Yes
Brooks et al[58]	43	42	2004	Yes	Wallstent/Dynalink	None	Yes
CAVATAS:[20]	251	253	2001	Yes	Variable	None	Yes
CARESS[3]†‡	254	143	2003	Yes	Wallstent	Guardwire Plus	Yes
SAPPHIRE[4]	167	167	2004	Yes	Smart/Precise	Angioguard	Yes
EVAS-3S[8, 59]*†	150	150	2004	Yes	Multiple	Multiple	Yes
CREST[5]*†	1250	1250	—	—	Acculink	Accunet	Yes
ICSS[6]*†	750	750	—	—	Multiple	Multiple	Yes
CAVATAS II[60]*†	233	233	—	—	Multiple	Multiple	Yes
ACT I[9]*†	750	750	—	—	Xact	Emboshield	Yes
SPACE[7]†*	430	430	—	—	Acculink	Accunet	Yes

CAS, Carotid artery stenting, *CEA,* carotid endarterectomy; *Neuro MD,* independent neurologic evaluation by neurologist; *MI,* myocardial infarction; *EPD,* embolic protection device.
Stent type or EPD type reported as "multiple" if there was not a dominant type used.
*Trial currently ongoing.
†Number of patients listed represents the number planned for enrollment.
‡Not randomized. Patients assigned via "selection criteria reflective of broad clinical practice."
§CAS stroke rate based on first 80 patients in CAS arm.

Table IV. Embolic protection devices commonly utilized in carotid artery stenting

Device	*Manufacturer*	*Mechanism*	*Trials/reports*	*Profile (Fr)*
Filterwire	Boston Scientific	Wire-deployed basket with filter	BEACH[52], CABERNET[53]	3.2
Interceptor	Medtronic	Wire-deployed basket with filter	MAVERiC[50]	2.9
Angioguard	Cordis	Wire-deployed basket with filter	SAPPHIRE[4]	3.2-3.7
Spider	EV3	Wire-deployed basket with filter	CREATE[51]	2.9
Rubicon	Rubicon	Wire-deployed basket with filter	RULE-Carotid[61]	2.1-2.7
Accunet	Guidant	Wire-deployed basket with filter	ARCHER[48], SPACE[7], CREST[5]	3.5-3.7
Emboshield	Abbott	Wire deployed basket with filter	SECuRITY[47]	2.9-3.3
Guardwire	Medtronic	Occlusion balloon and aspiration catheter	CARESS, SHELTER[54]	2.8
MOMA	Invatec	Common carotid flow blockage balloon system	Coppi et al[62], Reimers[63]	N/A
Parodi Anti-Embolic System	Gore	Common carotid flow blockage balloon system with flow reversal	Parodi et al[64]	N/A

factors, but this has not been established by comparison studies, so that EPD selection is currently based on individual practitioner experience.

Approval and reimbursement for stents and EPDs in the United States. The FDA approved the Guidant Acculink/Accunet CAS system in August 2004[14] and the Abbott Xact/Emboshield CAS system in September 2005.[18] These devices were approved for limited application, specifically for symptomatic patients with ≥50% internal carotid artery stenosis or asymptomatic patients with ≥80% internal carotid artery stenosis who are considered to be at high risk for CEA. In this regard, patients can be at high physiologic risk for CEA because of risk factors such as severe coronary artery or pulmonary disease, end-stage renal disease, and uncontrolled diabetes mellitus.[14] Patients can also be at high anatomic risk for CEA because of risk factors such as contralateral internal carotid artery occlusion, radiation treatment to the neck, distal internal carotid artery location, spinal immobility, tracheostomy stoma, or contralateral laryngeal nerve paralysis.[14] Ongoing randomized trials will determine effectiveness of CAS in lower-risk populations, but until these results are available, precise definitions of high-risk patients appropriate for CAS are being determined by these broad guidelines combined with individual practitioner experience.

Currently CAS is reimbursed by the Center for Medicare and Medicaid Services (CMS) only for FDA-approved devices. In addition, CMS will reimburse only for treatment of symptomatic, high-risk patients with >70% stenosis in CMS-approved centers. Additionally, in approved clinical trials, CMS will reimburse for symptomatic, high-risk patients with 50% to 69% stenosis and asymptomatic

Table III. Continued.

	30-day stroke %		*30-day death %*		*30 day MI %*		*30-day combined outcome*	
Follow-up	*CAS*	*CEA*	*CAS*	*CEA*	*CAS*	*CEA*	*CAS*	*CEA*
30 days	71	0						
1 year	12.1	3.6						
30 days	0	0.0	0	3.0				
2 years	0	0	0	0				
30 days	8.0	8.0	3.0	2.0	—	—	10.0	9.9
30 days	2.1	3.6	0.0	0.4	0.0	0.8	2.1	4.4
2 years	3.6	3.1	1.2	2.5	2.4	6.1	4.8	9.8
4 years	8.6§							
4 years	—	—	—	—	—	—	—	—
30 days	—	—	—	—	—	—	—	—
5 years	—	—	—	—	—	—	—	—
1 year	—	—	—	—	—	—	—	—
30 days	—	—	—	—	—	—	—	—

patients with >80% stenosis. Furthermore, all such cases must be entered into a registry to track outcome for potential CMS review. In this regard, the Society for Vascular Surgery has established a registry that meets these requirements and which should provide useful future data.[19]

Variation in reporting. Evaluation of current case series, industry-sponsored registries, and randomized trials reveals variation in study design and outcome measurement:

First, duration of follow-up varies from 30 days in the Carotid and Vertebral Artery Transluminal Angioplasty Study-I (CAVATAS-I),[20] 1 year in SAPPHIRE,[4] and up to 2 years in Prospective Registry of Carotid Angioplasty and Stenting (Pro-CAS),[21] albeit some of this variation simply represents differences in the current stage of result reporting. Although inherent differences in follow-up duration are likely, it becomes difficult to compare outcomes across trials with such distinct differences.

Second, outcome event measurement has not been standardized. For example, SAPPHIRE classified strokes as minor and major, according to the National Institutes of Health Stroke Scale. CAVATAS, meanwhile, divided major adverse outcomes into "disabling stroke or death" or "stroke lasting more than 7 days."

Third, primary endpoints have also varied. ARCHeR 1 and 2 considered all deaths, strokes, and myocardial infarctions at 30 days and ipsilateral strokes until 1 year as primary end points, but ARCHeR 3 reported only all deaths, strokes, and myocardial infarctions at 30 days. Reporting standards need to be established to allow comparison and interpretation across studies.

CONCLUSIONS

As with other minimally invasive surgical procedures, CAS has developed rapidly over the last decade. Although equivalency with CEA has been established in high-risk patients, the effectiveness of CAS in lower-risk patients is not yet established. However, the choice of CEA vs CAS in individual patients is currently based more on individual practitioner experience than on clear evidence-derived guidelines. Nonetheless, the popularity of less invasive therapy combined with marketing of new CAS systems has increased the utilization of CAS. Ongoing randomized trials will help determine optimal carotid revascularization strategies in the future.

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